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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/159,680 09/24/98 PATTERSON

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HM12/1108

EXAMINER

GOLDBERG, J

ART UNIT

PAPER NUMBER

1614

B

DATE MAILED:

11/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/159,680

Applicant(s)
Patterson

Examiner
Jerome D. Goldberg

Group Art Unit
1614



☒ Responsive to communication(s) filed on 09/08/99 and 09/23/99

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-9 and 11-21 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 21 if in independent form is/are allowed.

☒ Claim(s) 1-9 and 11-20 is/are rejected.

☒ Claim(s) 21 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948:

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1614

The finality of this Office action of June 24, 1999 is herein withdrawn and the following actions given. It is noted the Dr. Sean Duffy declaration is now completed and ~~the rejection is now completed and~~ the rejection under 35 U.S.C. 103 is herein withdrawn.

Claims 1-9 and 11-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific polyethylene glycol disclosed, does not reasonably provide enablement for the term "polyethylene glycol." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The term "polyethylene glycol" in claims 1-9 and 11-20 lacks clear exemplary support in the specification as filed. The term is so broad as to read polyethylene glycols that are ineffective. The Dr. Sean Duffy declaration on page 5, lines 9-12 states that "the increase in viscosity renders PEG 400 completely unsuitable for use in the composition of this invention in terms of manufacture (elongated filter times), syringeability of the parenteral product and the potential of irritancy to the target animal." In view of Dr. Duffy's remarks, it is clear that all PEG compound will not work. Changing the PEG compound in the claims to the PEG 200 would overcome this rejection.

Claim 21 is objected to as depend on a rejected claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1614

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner J. D. Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday-Thursday from 9:00 a.m. to 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

J. Goldberg; CV

11/1/99



JEROME D. GOLDBERG
PRIMARY EXAMINER
GROUP 1250